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10/628,296	07/28/2003	Lian-Chao Li	P06331US01	4176

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DES MOINES, IA 50309-2721

EXAMINER
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KUMAR, VINOD

ART UNIT	PAPER NUMBER
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1638

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02/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/628,296

Applicant(s)

LI ET AL.

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on November 12, 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30,35 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30,35 and 38-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of objections and rejections***

1. Office acknowledges the receipt of Applicant's response filed November 12, 2007. The amendment filed November 12, 2007 has been entered.

Claims 1-29, 31-34, 36-37 are cancelled.

Claims 30, 35, and newly added claims 38-44 are pending.

Newly added claims 38-44 fall within the scope of elected Group IV.

Claims 30, 35 and newly added claims 38-44 are examined on merits in this Office action.

Rejection of claims 30 and 35 under 35 U.S.C. 102(b) is withdrawn in light of claim amendment filed in paper of November 12, 2007.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made FINAL.

### ***Election/Restriction***

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

3. Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 is directed to a solution having pH from about 4.0 to about 7.5, whereas the dependent claim is directed to water. It is important to note that water can have a pH of more than 7.5. For example, tap water has pH of 8.0. Claim 30 fails the infringement test because claim 42 would conceivably be infringed by water would not infringe claim 30. See MPEP § 608.01(n).

***Claim Rejections - 35 USC § 112***

4. Claims 30, and 35 remain rejected and newly added claims 38-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solution having pH of 4.5 to 5.5, and comprising an isolated group 2/3 pollen allergen of SEQ ID NO: 2 (Lol p 3) with  $\beta$ -expansin activity in the solution to expand monocot cell walls, does not reasonably provide enablement for a solution (a) comprising any group 2/3 pollen allergen and (b) having pH from about 4.0 to about 7.5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the

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reasons of record stated in previous Office actions and for additional reasons as stated below. Applicant traverse the rejection in the paper filed November 12, 2007.

Applicant argues that one of ordinary skill in the art would be able to identify and isolate group 2/3 allergens having  $\beta$ -expansin activity using standard techniques. Applicant cites declaration filed under 37 C.F.R. § 1.1.32 to support the argument that group 2/3 allergen from other plant species (e.g. maize) can be used to achieve the same results of cell wall expansion. Applicant further argues that the specification teaches a solution (pH of about 4.0 to about 7.5) comprising an isolated group 2/3 allergen having  $\beta$ -expansin activity is useful for the expansion of plant cell wall (response, page 5, line 11 through the end of 2<sup>nd</sup> paragraph of page 6).

Applicant's arguments were fully considered but were not found to be persuasive. Applicant's attention is drawn to Fig. 8, wherein it is clearly disclosed that pH of about 4.0 or pH of about 7.0 did not result in any cell wall expansion. It is also noted that at pH greater than 5.5 a significant drop in cell wall extension activity was observed. It is also noted that results presented in Fig. 8 are directed only to Lol p 3 (SEQ ID NO: 2).

Applicant's attention is also drawn to page 4, lines 22-24, wherein Applicant admits that Lol p 3 will have commercial application in cell wall applications where pH of the solution is greater than 5. However, data presented in Figure 8 shows significant drop in cell wall expansion activity at pH above 5.5, which is encompassed by the claim.

Furthermore, the specification lacks guidance on a solution that would be useful for cell wall expansion comprising a group 2/3 pollen allergen having expansin activity (other than SEQ ID NO: 2), and wherein the pH is in the range of about 4.0 to about 7.5.

It is important to note that the recitation "pH about 4.0 to about 7.5" would encompass pH at which the instantly claimed solution would not exhibit plant cell wall expansion activity. It is also important to note that the recitation "about" would encompass pH values above 4.0 or 7.5.

In the absence of adequate guidance, it is maintained that undue experimentation would have been required at the time the claimed invention was made to determine how to use any group 2/3 pollen allergen having  $\beta$ -expansin activity in plant cell wall expansion when present in a solution having pH from about 4.0 to about 7.5. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

5. Claims 42-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 42 recite "water solution" which introduces **NEW MATTER** into amended claims. The specification does not provide written description support for "water solution" comprising the limitations of claim 30. It is important to note that water can have a pH of more than 7.5. For example, tap water has pH of 8.0. This does not comply with written description requirements.

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Claim 43 recite the phrase "pH of said solution has been adjusted with acetic acid" which introduces **NEW MATTER** into amended claims. The specification does not provide written description support for "pH of said solution has been adjusted with acetic acid". This does not comply with written description requirements.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 30, 35 remain, and newly added claims 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosgrove (Nature, 407:321-326, Published September 21, 2000, Applicant's IDS) in view of McQueen-Mason et al. (Plant Physiol.,

107:87-10, 1995, Applicant's IDS) and Ansari et al. (Biochemistry, 28:8665-8670, 1989).

This rejection has been necessitated due to the claim amendment filed in the paper of November 12, 2007.

Claims are broadly drawn to a solution useful for the expansion of a plant cell wall comprising an isolated group 2/3 pollen allergen having  $\beta$ -expansin activity in solution and wherein said solution has a pH from about 4.0 to about 7.5, or wherein said group 2/3 allergen having  $\beta$ -expansin activity is not effected by DDT, or wherein said pH is from about 4.5 to about 5.5, or wherein said group 2/3 pollen allergen having  $\beta$ -expansin activity has more than one aromatic residue on its protein surface, or wherein said group 2/3 pollen allergen comprises SEQ ID NO: 2, or wherein said group 2/3 pollen allergen comprises comprise SEQ ID NO: 5 at its N-terminal twenty amino acids of said allergen, or wherein said solution is water, or wherein pH of said solution is adjusted with pH or wherein said solution comprises a plant cell.

Cosgrove teaches a solution having pH 4.5, and comprising plant cells (e.g. cucumber cells) and  $\beta$ -expansins. The reference further teaches using said solution in studying plant cell wall expansion (pg 322, figure 1; paragraph bridging pg 322 and 323). The reference further teaches a group 2 pollen allergen having  $\beta$ -expansin activity and comprising more than one aromatic amino acid residues on the protein surface. (pg 325, left column, line 2-29).

Cosgrove does not teach a solution comprising a group 2/3 pollen allergen and plant cells to study expansion of a plant cell wall.



McQueen-Mason et al. teach using a solution having pH 4.5, and comprising plant cells (cucumber cells) and expansins to study plant cell wall expansion (pg 87, abstract; pg 89, materials and methods; page 91, figures 2-3; page 93). The reference also teaches that pH of the solution was adjusted with acetic acid (page 89, see under viscometric assay in left column, lines 6-9).

Ansari et al. teach a solution (a protein preparation) comprising Rye Grass pollen allergen (a group 2/3 allergen) encoding a polypeptide which has 100% amino acid sequence identity to instant SEQ ID NO: 2, wherein N-terminal amino acid sequence of said polypeptide has sequence identity to instant SEQ ID NO: 15. See in particular, page 8665, abstract and introduction; page 8667, figure 1; page 8668, figure 2; page 8668, paragraph 1<sup>st</sup> of discussion.

At the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to modify Cosgrove solution by replacing expansins with a group 2/3 pollen allergen including those taught by Cosgrove et al. or Ansari et al. to study the role of group 2/3 pollen allergen in cell wall expansion.

Given that Cosgrove suggests that group 2 pollen allergen may be involved in cell wall loosening because of their homology to  $\beta$ -expansins and secretion to the cell wall by grass pollen (last paragraph bridging pages 324 and 325), one of ordinary skill in the art would have been motivated to replace expansins of the solution taught by Cosgrove or McQueen-Mason et al. with a group 2/3 pollen allergen of Ansari et al. in arriving at the instantly claimed invention with reasonable expectation of success. One of the ordinary skill in the art would have been motivated to do so for the purpose of

studying the roles of group 2/3 pollen allergens in cell wall expansion with reasonable expectation of success.

One of the ordinary skill in the art would have obviously realized that  $\beta$ -expansins activity of group 2/3 pollen allergen would not have been affected by DTT because the group 2/3 pollen allergen of SEQ ID NO: 2 as taught by Ansari et al. lacks cysteine residues.

Given,  $\beta$ -expansins showed higher activities under acidic conditions of pH 4.5, it would have been obvious for one skilled in the art to adjust the pH of a solution containing a group 2/3 pollen allergen of Ansari et al. to pH 4.5 using any pH lowering acid including an acetic acid as taught by McQueen-Mason et al. to obtain plant cell wall expansion with reasonable expectation of success.

Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

### ***Conclusions***

7. Claims 30, 35, and 38-44 are rejected.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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PRIMARY EXAMINER  
12/6/07